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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/687,575	10/13/2000	Rima Kaddurah-Daouk	AVZ-007CP3RCE	9336

959 7590 03/26/2008  
LAHIVE & COCKFIELD, LLP  
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BOSTON, MA 02109-2127

EXAMINER
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RAHMANI, NILOOFAR

ART UNIT	PAPER NUMBER
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1625

MAIL DATE	DELIVERY MODE
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03/26/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/687,575	<b>Applicant(s)</b> KADDURAH-DAOUK ET AL.	
	<b>Examiner</b> NILOOFAR RAHMANI	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on RCE, filed on 02/06/2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 86, 91, 93, 95, 98-100, 133 and 135-140 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 86, 91, 93, 95, 98-100, 133, and 135-140 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. This application is RCE, filed on 02/06/2008. Claims 86, 91, 93, 95, 98-100, 133, and 135-140 are pending in the instant application. Claims 1-85, 87-90, 92, 94, 96-97, 101-132, and 134 are cancelled.

#### ***Priority***

2. This application is filed on 10/13/2000, which is a CIP of application # 09/285,395, filed on 04/02/1999 (ABN), which is a CIP of 09/283,267, filed on 04/01/1999 (ABN), which claims benefit of 60/080,459, filed on 04/02/1998. A priority claims for the filing date of PCT application PCT/US99/07340 is in the application, but this document is not included in the file. For the claims to be completely valid, applicants must provide the priority document.

3. The rejection of claims 86,93,95,98,100,108,115,117,120,122,133-134 under 35 U.S.C. 102(e) and 35 U.S.C. 103(a) over Blass et al., US 6,537,969 is withdrawn for reason of applicants argument in paper dated 02/06/2008.

4. The rejection of claims 108,113,115,117,120-122, and 134 under 35 U.S.C. 112, first paragraph is withdrawn for reason of cancellation of the claims in paper dated 02/06/2008.

5. The rejection of claims 86, 91, 93, 95, 98-100, 133, and 135-140 under 35 U.S.C. 112, first paragraph is maintained for reason of record. Applicants argue that the working examples are not required. Applicants also argue that at least at page 3, lines 22-28, page 8, lines 22-25, and page 74, lines 9-14 are described the method of using the combinations of the invention to treat nervous system

diseases. furthermore, the effectively of creatine on the MPTP mouse model of Parkinson's disease is accepted by the scientific community as evidence of the effectively of creatine as a potential treatment of Parkinson's disease.

It is the examiner's position that the Example 2 is prophetic example. On page 54, line 36 to page 56, line 10 of the specification, applicant has mouse models of Parkinson's disease such as MPTP. On figure 4, the doses of using creatine and neuroprotective effects against MPTP measuring protein synthesis. However, applicant has not guidance or examples for treating Parkinson's disease using pharmaceutical composition of a combination of creatine, creatine phosphate or a creatine compound and a neuroprotective agent. Nor does applicants have any examples of MPTP model of the instant compounds working on the MPTP model. Applicants also have shown in the declaration that creating is in Phase III clinical trials. Therefore, applicants have not shown the scope of the claims, which comprising of creatine, a creatine phosphate or creatine compounds and a neuroprotective agent.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory

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action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

**6.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Niloofar Rahmani whose telephone number is 571-272-4329. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NILOOFAR RAHMANI

03/13 /2008

/D. Margaret Seaman/

Primary Examiner, Art Unit 1625